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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,379	11/19/2003	Bruce M. Frankel	7177USO1	6700

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EXAMINER	
RAMANA, ANURADHA	
ART UNIT	PAPER NUMBER
3775	

NOTIFICATION DATE	DELIVERY MODE
01/15/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents_Abbott_Park@abbott.com
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Office Action Summary	Application No.	Applicant(s)	
	10/717,379	FRANKEL ET AL.	
	Examiner	Art Unit	
	Anu Ramana	3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,21-28 and 31-53* is/are pending in the application.

4a) Of the above claim(s) *1-14,21,22 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-28 and 31-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 22, 2008 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 23, 24, 26 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Li et al. (US 6,610,079).

Li et al. disclose a method of introducing a fluid into bone including the steps of: advancing a rivet or "bone tap" 70 into bone, the rivet having screw threads and openings; introducing fluid or polymer or "bone cement" into the surrounding bone through openings in the bone tap; and introducing a fastener such as a suture through an opening formed by the bone tap (Figs. 1B, 4B, 5A and 6, col. 2, lines 58-61, col. 7, lines 58-67, col. 8, col. 9 and col. 10, lines 1-16).

Claims 33-34, 36-38, 40, 42, 44-47, 49 and 51-53 are rejected under 35 U.S.C. 102(e) as being anticipated by Daniel et al. (US 6,622,731).

Daniel et al. disclose a method of introducing fluid into bone including the steps of: advancing an introducer or "bone tap" 292 into bone, the bone tap including a passage and one or more openings (312) communicating with the passage and threading (310) located near a distal end of the bone tap; introducing fluid or "cement" through the bone tap utilizing a fluid delivery system such as a syringe; and coupling a handpiece or "driver" to the bone tap to remove the bone tap from bone (Figs. 22-24C, col. 20, lines 25-59, col. 21, lines 59-67, cols. 22-23 and col. 24, lines 1-3).

The steps of: introducing fluid to a first location; moving the bone tap and introducing fluid to a second location are inherent in the disclosure of Daniel et al. since a patient could have multiple sites requiring treatment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. (US 6,610,079) in view of Tague et al. (US 6,599,293).

Li et al. disclose all elements of the claimed invention except for providing a medicament or drug in the bone cement.

It is well known to mix antibiotics or other desired drugs in bone cement so that when the bone cement is applied to a specific surgical site, the drugs leach out and are delivered directly to the surgical site as demonstrated by Tague et al. (col. 1, lines 32-37).

Accordingly it would have been obvious to have mixed a desired drug into the bone cement prior to delivery of the bone cement utilizing the method of Li et al. since it was well known in the art to mix a specific drug in bone cement prior to delivery of the

bone cement to a specific surgical site so that the drug is delivered directly to the surgical site.

The method steps of claim 25 are rendered obvious by the above discussion.

Claims 35, 43 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniel et al. (US 6,622,731) in view of Tague et al. (US 6,599,293).

Daniel et al. disclose all elements of the claimed invention except for providing a medicament or drug in the bone cement.

It is well known to mix antibiotics or other desired drugs in bone cement so that when the bone cement is applied to a specific surgical site, the drugs leach out and are delivered directly to the surgical site as demonstrated by Tague et al. (col. 1, lines 32-37).

Accordingly it would have been obvious to have mixed a desired drug into the bone cement prior to delivery of the bone cement utilizing the method of Daniel et al. since it was well known in the art to mix a specific drug in bone cement prior to delivery of the bone cement to a specific surgical site so that the drug is delivered directly to the surgical site.

The method steps of claims 35, 43 and 50 are rendered obvious by the above discussion.

Claims 28, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. (US 6,610,079).

Li et al. disclose all of the claimed steps except for: (1) partially or completely withdrawing the bone tap; and (2) introducing fluid to a first location, moving the bone tap and introducing fluid to a second location.

It is well known that during a surgical procedure if the chosen direction of insertion does not result in easy access to the target site, for example, due to the nature of the underlying bone, the surgeon would need to change the direction of insertion.

The claimed method steps are within the purview of obvious design choice because partial or complete withdrawal of the bone tap might be necessary if the surgeon made an error in placement of the bone tap. Further, moving from one location to another might require either complete or partial withdrawal of the bone tap, i.e, moving of the bone tap, depending on the proximity of the first and second locations, based on the nature of the underlying bone.

Claims 39, 41 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniel et al. (US 6,622,731).

Daniel et al. disclose all of the claimed steps except for partially withdrawing the bone tap.

It is well known that during a surgical procedure if the chosen direction of insertion does not result in easy access to the target site, for example, due to the nature of the underlying bone, the surgeon would need to change the direction of insertion.

The claimed method steps are within the purview of obvious design choice because moving to a specific location or moving from one location to another might require either complete or partial withdrawal of the bone tap, depending either on: (1) whether the surgeon made an error in approaching the target site; and/or (2) on the proximity of the first and second locations.

Response to Arguments

Applicant's arguments filed on October 22, 2008 have been fully considered.

Applicant's arguments with respect to the rejections over Gorek persuasive. Accordingly, this rejection is being withdrawn.

Applicant's arguments with respect to the rejections over Li et al. are not persuasive. The screw or rivet of Li clearly functions as a bone tap since it forms an opening in bone.

Applicant's arguments with respect to Daniel et al. are not persuasive since the introducer 292 functions as a bone tap. Daniel et al. clearly disclose introducer 292 to

have a threaded section 310 to allow the introducer to be screwed or tapped into bone. Daniel et al. also disclose that all or a portion of the threaded section can include apertures 312 to provide for irrigation of the threaded section during the screwing or drilling or "tapping" operations (col. 22, lines 37-62).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached on Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR
January 4, 2009

/Anu Ramana/
Primary Examiner, Art Unit 3775